

### **REMARKS**

In the Office Action dated December 2, 2003, claims 30-36 are pending and are under consideration. Claims 30-36 are rejected under 35 U.S.C. §112, first paragraph, as allegedly lacking enabling disclosure.

Claim 30 has been amended and claim 32 has been canceled without prejudice. No new matter has been added. Entry of these amendments is respectfully requested.

This response addresses the Examiner's rejection. Applicants respectfully submit that the present application is in condition for allowance. Favorable consideration of all pending claims is therefore respectfully requested.

### **REJECTION UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

The Examiner has rejected Claims 30-36 under 35 U.S.C. §112, first paragraph, as allegedly lacking an enabling disclosure. The Examiner alleges that it would require undue experimentation for one skilled in the art to make and use the invention. The Examiner also alleges on page 4 of the office action that the Applicant has provided little or no guidance relating to methods of inhibiting the proliferation of malignant breast cancer cells in mammals comprising administering OSM.

In response, Applicants respectfully submit that pending claims 30-36 were enabled at the time the present application was filed. The Examiner alleges on page 4 of the office action that a considerable amount of time of experimentation is permissible if the skilled artisan is given sufficient direction or guidance. Applicants respectfully submit that such direction and guidance are disclosed throughout the specification as follows:

Page 14, lines 5-15 discloses the amount of cytokine that can be administered to a mammal as well as the frequency of dosages. For instance, lines 7-9 disclose, as an example, that from about 0.5 micrograms to about 2 milligrams of cytokine per kilogram of body weight per day may be administered to a mammal.

Page 15, lines 6-14 discloses, as an example, the effective amount of a cytokine that can be administered to a mammal to treat breast cancer as well as the frequency of dosages.

Page 14, lines 17-26; page 15, lines 3-6; page 17, lines 27-30; and page 18, lines 1-4 disclose modes of administering cytokines.

Page 15, lines 7-30 and page 16, lines 1-30 disclose suitable forms containing cytokines, for injection or oral administration.

Based on the above disclosure in the specification, Applicants respectfully submit that the specification provides sufficient direction and guidance to the skilled artisan to practice methods of inhibiting the proliferation of malignant breast cancer cells in mammals comprising administering a cytokine of the present invention.

The Examiner also alleges that the basis for his rejection was previously set forth on pages 5-9 of the February 21, 2003 office action. In the February 21, 2003 office action, the Examiner argued that the specification does not provide any guidance or exemplification of any correlation between inhibiting proliferation of a breast cancer cell line in the presence of OSM *in vitro* and administering OSM to a mammal to inhibit the proliferation of malignant breast cancer cells *in vivo*. The Examiner concluded that one skilled in the art would be forced into undue experimentation to practice the claimed invention.

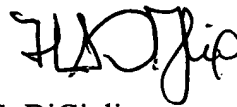
Applicants respectfully submit, for reasons stated above, that no undue experimentation is required to optimize the parameters for *in vivo* administration of a selected cytokine. Accordingly, those skilled in the art would consider that the *in vitro* characterizations provided in the specification are reasonably correlated to inhibitory effects of the selected cytokines on the proliferation of malignant breast cancer cells *in vivo*. Some experimentation is permissible. In re Wands, 858 F.2d 731, 736-737, 8 U.S.P.Q. 1400, 1404 (Fed Cir. 1988). Necessary experimentation is not determinative of the question of enablement; only undue experimentation is fatal under the provisions of 35 U.S.C. §112, first paragraph. Id. The specification, as outlined above, provides sufficient direction and guidance to the skilled artisan

to practice methods of inhibiting the proliferation of malignant breast cancer cells in mammals comprising administering a cytokine of the present invention.

Therefore, it is respectfully submitted that the rejection under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

In view of the foregoing remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



Frank S. DiGiglio  
Registration No. 31,346

SCULLY, SCOTT, MURPHY & PRESSER  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343

FSG/RLB:nis